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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,327	05/09/2001	Robert J. Levy	047172-0170	2799

110 7590 11/07/2003

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EXAMINER	
PRIEBE, SCOTT DAVID	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 11/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	**Application No.**	**Applicant(s)**	
	09/851,327	LEVY ET AL.	
	Examin r	**Art Unit**	
	Scott D. Priebe	1632	

--The MAILING DATE of this communication appears on the cover sheet with the corresp nd nce address --

THE REPLY FILED 27 October 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☒ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☒ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *27,28,33,35 and 36*.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1,3-5,34 and 37-39*.

   Claim(s) withdrawn from consideration: *2,6,10,11,13,17,19,20,22-25 and 29-31*.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☒ Other: *See Continuation Sheet*

Scott D. Priebe
Primary Examiner
Art Unit: 1632

Continuation of 2. NOTE: Proposed claim 37 fails to require the carrier to be a polymeric carrier as disclosed in the oringinal specification. The original specification does not support carriers as recited which are not polymeric.

Continuation of 5. does NOT place the application in condition for allowance because: Applicant points to Examples 1-3 using rat A10 cells as support for "vascular smooth muscle cell" in claim 34. While A10 cells are a species of vascular smooth muscle cells, it remains that the original specification does not mention even in passing of applying the method generically to vascular smooth muscle cells. Disclosure of a single species is rarely, if ever, sufficient to describe a broad genus, particularly when the specification fails to describe the features of that genus, even in passing. In re Shokal, 113 USPQ 283 (CCPA 1957); Purdue Pharma L.P. v. Faulding Inc., 56 USPQ2d 1481 (CAFC 2000). With respect to the enablement rejection, regardless of the type of vector used, the claims require that transfection be enhanced, presumably in comparison to an otherwise identical method lacking tenacin C. The specification provides evidence of such enhancement with plasmid vectors contained in cationic liposomes with cultured cells. That one of skill in the art is aware of other types of vectors in no way makes it predictable that transfection with such vectors would be enhanced by the same method that enchanced liposomal plasmid vectors. In regard to in vivo applications, the rejection sets forth reasons to doubt the the statements made in the specification including high unpredictablity, little guidance in the specification, and lack of working examples relevant to in vivo use. Applicant's arguments fail to address these issues, relying instead on general statements as to what techniques may be used without providing detailed guidance on how such prior art techniques are to be used in the context of the claimed invention. While every aspect of a generic claim need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable the skilled artisan to understand and carry out the invention. It is true that a specification need not disclose what is well known in the art. However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. The rule that a specification need not disclose that which is well known in the art simply means that omission of minor details does not cause a specification to fail the enablement requirement, and is not a substitute for an enabling disclosure. However, if there is no disclosure of starting materials and of conditions under which the process can be carried out, undue experimentation is required. Failure to provide such teachings can not be rectified by asserting that the disclosure of the missing necessary information was well known in the prior art. See Genentech Inc. v. Novo Nordisk A/S, 42 USPQ2d 101, 1005 (CA FC, 1997). The argument pertaining to Perlstein et al. is moot, since the exhibit has not been considered.

Continuation of 10. Other: Applicant has not cancelled claims drawn to inventions non-elected with traverse, as required in the final rejection.